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| Debi Whitson 26005 East 317 Street Harrisonville, MO 64701 | | | | |
| EXAMINER PORTER, RACHEL L | | | | |
| ART UNIT | | PAPER NUMBER | | |
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DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/802,546

Applicant(s)

WHITSON, DEBI

Examiner

Rachel L. Porter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the application filed 3/9/01. Claims 1-17 are pending.

Oath/Declaration

2. A new oath or declaration is required because it does not identify the citizenship of the inventor (a zip code appears where the citizenship should have been provided.) The wording of an oath or declaration cannot be amended. If the wording is not correct or if all of the required affirmations have not been made or if it has not been properly subscribed to, a new oath or declaration is required. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

Acknowledgement of a Third-Party Submission under 37 CFR 1.99

3. A third-party submission has been filed under 37 CFR 1.99 on 11/4/2002 in the published application.

To ensure that a third-party submission does not amount to a protest or pre-grant opposition, 37 CFR 1.99 does not permit the third party to have the right to insist that the examiner consider any of the patents or publications submitted. Furthermore, if the submission or part of the submission is not in compliance with 37 CFR 1.99, that noncompliant submission or part thereof will not be entered in the application file. Therefore, unless the examiner clearly cites a patent or publication on form PTO-892,

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Notice of References Cited and such reference is used in a rejection or its relevance is actually discussed during prosecution, consideration by the examiner of any patent or publication submitted in a third-party submission cannot be presumed.

If the applicant wants to ensure that the information in a third-party submission is considered by the examiner, the applicant should submit the information in an IDS in compliance with 37 CFR 1.97 and 37 CFR 1.98. An individual who has a duty to disclose under 37 CFR 1.56 should also submit any material information contained in a third-party submission to the Office in an IDS in compliance with 37 CFR 1.97 and 37 CFR 1.98 to ensure such material information is properly disclosed to the examiner.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 7, 12-13, and 15-16, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following recitations were not adequately described in the specification:

- Claims 7 and 15 recite converting and arranging the data stream to a defined set of data structures simulating the protocol or specification of ASTM.

- Claim 12 describes a scanner that accepts optical mark reader technology or character recognition technology.
- Claim 13 recites limitations regarding messaging with any database that accepts ASTM messaging.
- Claim 16 recites arranging the data stream to a defined set of data structures simulating the protocol of an ANSI-accredited Standards Developing Organization.

In particular, the Examiner was unable to locate portions of the originally filed specification that discuss or disclose any details of data stream conversion process as it relates to any format except HL7. Moreover, the details of the optical scanner are not discussed.

In response to this issue, the Applicant is respectfully requested to clarify the above issues and to specifically point out description and support for these limitations in the originally filed specification and/or drawings, or to cancel the new matter in the reply to this Office Action.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2,4,7-11,13, and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation " wherein the step of forming a basic patient medical record in a computer through entry of information using a keyboard... " There is insufficient antecedent basis for these limitations in these claims. Claim 1 does not recite a "step of forming a basic patient medical record" by a professional staff member or through use of a computer.

Claim 10 inherits the deficiencies of claim 2 through dependency and is therefore also rejected.

8. Claim 4 is rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph.

The claim is narrative in form and uses functional or operational language. The steps performed in a method or the structure that goes to make up any device must be clearly and positively specified. Furthermore, the claim(s) must be in one sentence form only. Note the format of the claims in the patent(s) cited.

In the present case, the claim includes multiple sentences, and it is unclear how the statement, "This questionnaire may be provided within the medical facility or mailed to the patient," affects the steps performed in the claimed method or whether this limitation is required for the claimed method. If the Applicant deems this information to be required as a part of the claimed method, Applicant might consider incorporating such material into the claim as a wherein clause (i.e. "...wherein said medical questionnaire is provided to the patient in a medical facility or mailed to the patient.")

Claim 11 inherits the deficiencies of claim 4 through dependency, and is therefore also rejected.

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9. Claim 7 recites "simulating the protocol of the ASTM (American Society for Testing and Materials)." However, the Examiner understands there to be several protocol standards established by ASTM. Therefore, it is unclear which simulated protocol the Applicant is referencing in the current claim.

Claim 15-16 inherit the deficiencies of claim 7 through dependency, and are therefore also rejected.

10. Claims 8 and 9 recites the limitation "wherein the step of transferring the protocol arranged data..." There is insufficient antecedent basis for these limitations in these claims. Claim 1 does not recite a "step of transferring" and further does not recite "protocol-arranged data."

Furthermore, claim 8 recites that "the step of transferring the data...includes the steps of using the invention..." It is unclear to the Examiner how this phrase is intended to further limit the invention and which steps the Applicant intends to incorporate with the inclusion of the phrase "the steps of using the invention."

Claims 13 and 17 inherit the deficiencies of claim 9 and 8 respectively through dependency, and are therefore also rejected.

Also claim 17 recites that "the computer process" has at least a "32 mg hard drive." The Examiner is unfamiliar with the units represented by "mg" in the computer arts. (The Examiner understands "mg" to be an abbreviation for a milligram.) For the purpose of applying art, the Examiner will interpret this claim to mean that the computer used is a standard PC.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1,3-5,9,11, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Kraftson et al (USPN 6,151,581-hereinafter Kraftson).

[claim 1] Kraftson discloses a process of allowing a patient to have limited input access to their electronic medical record comprising of the steps of forming a basic patient medical record in a computer application through entry of information using a machine-readable questionnaire, a scanner, and a computer application;

a) providing the patient with a machine readable questionnaire concerning their medical history, their environment, their symptoms, or other pertinent information for answering by the patient; (Figure 2A-2C; col. 5, line 65-col. 6, line 3)

b) interfacing the machine readable card with a scanning type machine to convert the patient's written answers to a data stream; (col. 5, lines 1-6; col. 6, lines 3-10)

c) arranging the data stream into a defined set of data structure simulating the protocol structure from a party having authorization to export data to the patient's medical record; (col. 6, line 5-10; col. 7, lines 3-10)

d) sending the formatted data to an assigned location for importing into the patient's medical record. (col. 6, lines 10-18)

[claim 3] Kraftson teaches a process wherein the step of forming a basic patient medical record is accomplished by the patient in providing this information by written responses on the questionnaire. (col. 6, lines 41-46; col. 6, line 58-col 7, line 2)

[claim 4] Kraftson teaches a process wherein the step of providing the patient with a machine readable questionnaire concerning their medical history, their environment, their symptoms and other pertinent information includes the step of providing the patient with a medical questionnaire including questions concerning the systems making up the human body with designated locations for patient responses and is accomplished by a member of the clinical staff. (Figures 2A-C; 3A-C; Figure 13)

[claim 5] Kraftson teaches a process wherein the step of interfacing the machine readable card with a scanner to convert the patient's written answers to a data stream includes the step of interfacing the machine readable card with a scanner type machine and is accomplished by a member of the clinical staff. (col. 7, lines 3-11)

[claim 9] Kraftson teaches a process further comprising a step of transferring the protocol-arranged data into the patient's electronic medical record housed in a database includes the steps of using an interface engine, which receives the protocol-arranged data from the location specified by the user and sending it to the

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database containing the patient's electronic medical record. (col. 7, lines 3-11; col. 13, lines 6-56)

[claim 11] Kraftson teaches a process wherein the machine-readable questionnaire is a paper answer sheet comprised of questions with designated areas for patient responses. (Figures 2A-C, col. 7, lines 3-11)

[claim 12] Kraftson teaches a process wherein the scanner reading machine is a scanner of optical mark reader technology or character recognition technology. (col. 11, lines 3-11)

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 2,8,10, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraftson as applied to claim 1 above, and further in view of Oyama et al (USPN 5,496,175).

[claims 2 and 10] Kraftson teaches a system/method of gathering and entering patient data into a patient database using professional staff members, (col. 6, lines 19-col. 7, line 25) but does not expressly disclose inputting information using a microcomputer compatible keyboard. Oyama discloses a questionnaire system wherein data gathering occurs using PC's with keyboards (col. 6, lines 21-36) At

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the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method/system of Kraftson with the teaching of Oyama to allow manual input of data using a keyboard. As suggested by Oyama, one would have been motivated to include these features to increase the diversity of information that may be input into the system from the questionnaire data. (col. 1, line 55-col. 2, line 2).

[claim 8] Kraftson teaches a process further comprising the step of transferring the protocol-arranged data into the patient's electronic medical record housed in a database, which includes the steps of using the invention to send the formatted data through the microprocessor to the location specified by the user. Kraftson stores formatted data so it may be sent for statistical analysis and to various modules desired by the user. (col. 7, lines 3-11, 43-49; col. 8, line 39-col. 9, line 16) However, Kraftson does not expressly using a microcomputer compatible keyboard. Oyama discloses a questionnaire system wherein data gathering occurs using PC's with keyboards (col. 6, lines 21-36) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method/system of Kraftson with the teaching of Oyama to allow manual input of data using a keyboard. As suggested by Oyama, one would have been motivated to include these features to increase the diversity of information that may be input into the system from the questionnaire data. (col. 1, line 55-col. 2, line 2).

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[claim 17] Kraftson teaches a process wherein the computer processor is a standard PC (col. 8, lines 60-63; col. 19, lines 21-25).

15. Claims 6-7 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraftson as applied to claim 1 above, and further in view of Official Notice.

[claims 6-7 and 13-16]

Kraftson discloses a survey system and method for obtaining patient information from a questionnaire (Figure 2A-2C; col. 5, line 65-col. 6, line 3) and converting the obtained information into a data stream (col. 6, line 5-10; col. 7, lines 3-10), but does not expressly disclose the specific formats that are accommodated by the system. However, it is noted that HL7, ANSI, and ASTM are well known in the art for establishing transmitting and formatting standards for data. At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method/system of Kraftson to accommodate HL7, ANSI or ASTM protocol standards. One would have been motivated to include this feature to facilitate the transmission, storage, and analysis of patient data, as suggested by Kraftson (col. 2, lines 56-63).

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Brill (USPN 5,435,324) teaches a method for surveying patients for outcome analysis studies.

- Dewey et al (5,084,819) discloses a system and method for data collection of survey responses.

17. An examination of this application reveals that applicant is unfamiliar with patent prosecution procedure. While an inventor may prosecute the application, lack of skill in this field usually acts as a liability in affording the maximum protection for the invention disclosed. Applicant is advised to secure the services of a registered patent attorney or agent to prosecute the application, since the value of a patent is largely dependent upon skilled preparation and prosecution. The Office cannot aid in selecting an attorney or agent.

A listing of registered patent attorneys and agents is available on the USPTO Internet web site <http://www.uspto.gov> in the Site Index under "Attorney and Agent Roster." Applicants may also obtain a list of registered patent attorneys and agents located in their area by writing to the Mail Stop OED, Director of the U. S. Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel L. Porter whose telephone number is (571) 272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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